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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,195	07/23/2001	Kathleen C.M. Campbell	SIU 7396	2942

321 7590 08/23/2004  
SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER  
COOK, REBECCA

ART UNIT 1614	PAPER NUMBER
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DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/911,195	CAMPBELL, KATHLEEN C.M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rebecca Cook	1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,15,20-29 and 32-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,15,20-29 and 32-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/15/04</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 15, 2004 has been entered.

The requirement for an election of species has been withdrawn.

### ***Priority***

No support is seen in the parent applications for the instant method of use.

### ***Claim Rejections - 35 USC § 112***

Claims 3-4, 15, 21-29, 32-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 1 for the following compounds of claim 3: methioninol, hydroxy methionine and adenosyl-L-methionine.

In claims 42, 57 and 71 the proviso "provided that, at the same time said otoprotective agent is administered, an antineoplastic effective dose of cisplatin has not been prescribed for administration to said patient" is confusing. It is not clear that the patient has received or is receiving cisplatin.

Dependent claims 4, 15, 21-29, 32-37, 39-41, 44-56, 58-70 and 72-74 should begin with the word "The" and not "A" to make their dependent status clear.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 20-22, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell. Campbell discloses a method of using D-methionine to protect against ototoxicity caused by cisplatin. The instant claim recite that the ototoxicity is caused by noise. However, it would be inherent that that the methionine would protect the subset of patients receiving methionine to prevent or treat ototoxicity caused by cisplatin who are exposed to noise that would also result in ototoxicity.

Applicant argues that there is no disclosure by Campbell that shows that any of the rats were exposed to a level of noise that would cause ototoxicity or that one would design an experiment to expose rats to a significant level of noise. This is not persuasive. The instant method does not have to have been recognized in order for it to be inherent.

Claims 1, 3-4, 20-22, 29, 34, 42-44 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by 6,649,621 (Kopke et al). Kopke discloses (column 3, lines 9-12, Example 6) a method of using D-methionine and N-acetyl cysteine (NAC) to prevent and treat hearing loss due to noise.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 23-28, 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al.

Campbell discloses a method of using D-methionine to protect against ototoxicity caused by cisplatin. The instant claim recite that the ototoxicity is caused by noise. They further differ over Campbell in reciting L-methionine, dosage and dosage regimens. However, it would be inherent that that the methionine would protect the subset of patients receiving methionine to prevent or treat ototoxicity caused by cisplatin who are exposed to noise that would also result in ototoxicity. Furthermore, once a method of use is known, it is within the skill of the artisan to determine the optimum dosage and dosage regimens. Additionally, it would be obvious that the L-isomer would have the same use as the D-isomer.

Claims 15, 23-28, 32-33, 35-38, 40-41, 45-50 and 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,649,621 (Kopke et al). Kopke discloses (column 3, lines 9-12, Example 6) a method of using D-methionine N-acetyl cysteine to prevent and treat hearing loss due to noise. The instant claim differ over Kopke in reciting L-methionine, dosage and dosage regimens. However, once a method of use is

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known, it is within the skill of the artisan to determine the optimum dosage and dosage regimens. Additionally, it would be obvious that the L-isomer would have the same use as the D-isomer.

The Declaration of June 15, 2004 by Dr. Campbell is unsigned and is therefore not probative, but if it were signed it would not be persuasive over Campbell or Kopke, since it is opinion only.

In view of applicant's argument regarding "toneburst stimuli" the earlier rejection under 35 USC 103(a) over Campbell is withdrawn.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

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Rebecca Cook

A handwritten signature in cursive script, appearing to read "Rebecca Cook".

Primary Examiner  
Art Unit 1614

August 19, 2004